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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,040	03/01/2002	Joseph C. Cauthen	08442.0002-04	8078

22852 7590 10/17/2005

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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 10/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/085,040	Applicant(s) CAUTHEN, JOSEPH C.	
	Examiner Urmi Chattopadhyay	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2005 and 04 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 102-182 is/are pending in the application.
- 4a) Of the above claim(s) 108, 134-136, 140, 143, 144, 150, 176-178 and 182 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 102-107, 109-133, 137-139, 141, 142, 145-149, 151-175 and 179-181 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/15/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Species 1a and Species 2a with traverse in the reply filed on 8/4/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The examiner agrees that in addition to claims 102 and 141, claims 106, 114, 130, 148, 156 and 172 are generic to the present invention.
2. Claims 102-182 are currently pending. Claims 108, 134-136, 140, 143, 144, 150, 176-178 and 182 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. The claims being considered for further examination on the merits are claims 102-107, 109-133, 137-139, 141, 142, 145-149, 151-175 and 179-181.

Information Disclosure Statement

3. The Information Disclosure Statements filed 4/18/05 and 6/15/05 have been entered. The IDS filed 6/15/05 includes the PTO-1449 corresponding to the IDS filed 4/18/05. The references cited therein have been considered and an initialed and signed copy of the PTO-1449 is enclosed.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 102 and 141 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 102 and 141 require “*at least one extension*”. In at least [038] of the specification, applicant discloses the device as having a *pair* of lateral extensions, specifically left lateral extension (20) and right lateral extension (22). Two lateral extensions are clearly shown in the figures as well. The claimed limitation of “at least one extension” is broader in scope than what is disclosed by the applicant as the invention because it includes an embodiment where the device includes only one lateral extension. This embodiment is neither disclosed nor enabled by the specification. The written description requirement, therefore, has not been met.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 102-107, 109-133, 137-139, 141, 142, 145-149, 151-175 and 179-181 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bao et al. (USPN 6,224,630 as cited in applicant's IDS) in view of Gilson (USPN 5,904,703, as cited in applicant's IDS).

Bao et al. discloses a device with all the elements of claims 102 and 141, but is silent to the at least one extension being constructed such that the axis can flexibly deflect from its

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respective reference plane, as required by claims 102 and 141, and to at least one receptacle configured to receive a fixation element, as further required by claim 141. See column 2, lines 58-64 for a device for treatment of an intervertebral disc wall. See columns 7-8, lines 61-9 for the device comprising a spool-like configuration, which has main body portion (barrel) and two enlarged end portions. The enlarged end portions provide as extensions having an axis projecting along a respective reference plane, which reference plane extends substantially laterally from the main body portion. See column 14, lines 14-30 for at least one fixation element configured to extend at least partially into annular tissue. See column 14, lines 1-8 for the device being inserted and positioned within the annulus using a cannula. Gilson teaches an occluder device that is structurally capable of treating an intervertebral wall. The occluder device (60) comprises a spool-like configuration with a main body (6) and at least one lateral extension (5) having an axis projecting along a respective reference plane. The lateral extension (5) is constructed such that the axis can flexibly deflect from its respective reference plane in order to for the device (60) to be folded for loading in a catheter for deployment. See Figure 14 and column 6, lines 16-23. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Gilson to modify the device of Bao et al. by having the at least one extension constructed such that the axis can flexibly deflect from its respective reference plane in order to for the device (60) to be folded for loading into the cannula for deployment. Gilson also teaches the occluder device having a receptacle (11) with a slot running therethrough and unitary with main body (6) and extension (5) in order for the device to be engagable with an associated guidewire for movement of the device through a catheter for deployment. See Figure 3, column 3, lines 28-30 and column 4, lines 42-53. This receptacle

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(11) with slot allows the user to reposition the device within the sheath arrangement before releasing the device from the delivery catheter if the initial position was not the desired or optimal one. See column 5, lines 26-32. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Gilson to modify the device of Bao et al. by including a receptacle with a slot running therethrough (claim 142) unitary with the main body portion and extension (claim 155) in order for the device to be engagable with an associated guidewire for movement of the device through the cannula for deployment. This would be advantageous over using the expulsion rod of Bao et al. (column 14, lines 4-6) because this receptacle (11) with slot would allow the user to reposition the device within the cannula before releasing the device therefrom if the initial position was not the desired or optimal one. Gilson also teaches the device having first and second extensions (72) that lie in the same reference plane when undeflected in order to facilitate the collapsing of the device for delivery through a catheter. See Figure 16 and column 6, lines 28-33. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Gilson to modify the device of Bao et al. by including first and second extensions (72) that lie in the same reference plane when undeflected in order to facilitate the collapsing of the device for delivery through the cannula (claims 137-139 and 179-181).

Claims 103-105 and 145-147, see column 14, line 23 for biodegradable sutures. It is obvious that the sutures would comprise one knot because it is well known to knot sutures to prevent them from coming out or pulled apart.

Claims 106 and 148, see column 11, lines 36-41 for the main body being shaped to form a compatible fit with at least a portion of the edges of the aperture in the intervertebral disc wall.

Claims 107 and 149, see column 7, line 65 for the device comprising a spool-like configuration, which clearly suggests an extension of substantially uniform thickness. This limitation is also taught by Gilson in Figure 14.

Claims 109-111 and 151-153, see column 14, lines 14-23 for fixation elements that are known equivalents in the art.

Claims 112, 113 and 154, see column 7, line 65, column 8, lines 16-21 and column 14, lines 14-23 for the main body portion, extension and fixation element being formed as a unitary (whole) device.

Claims 114, 115, 118, 120, 124, 125, 156, 157, 160, 162, 166 and 167, see column 5, line 37 and column 6, lines 40-44 for the device comprising a biodegradable polymer matrix from collagen fibers.

Claims 116, 117, 121-123, 158, 159 and 163-165, see column 7, lines 34-37 and column 14, line 21 for the device comprising a biocompatible, polymeric membrane/fabric/sheet/mesh.

Claims 119 and 161, see column 5, lines 57-58 and column 10, line 64 for ePTFE.

Claims 126 and 168, see column 4, lines 50-54 for the device comprising a hygroscopic material.

Claims 127, 129, 169 and 171, see column 9, lines 18-40 for the device comprising growth factors to facilitate regeneration of disc tissue.

Claims 128 and 170, see column 9, lines 18-22 and column 10, line 61 for bioactive silica-based material.

Claims 130 and 172, see column 14, lines 3-8 for the device being flexibly resilient.

Claims 131 and 173, see columns 2-3, lines 64-7 for a portion of the device being porous.

Claims 132 and 174, see column 10, lines 57-60 for at least a portion of the device being non-porous.

Claims 133 and 175, see column 11, lines 36-41 and column 14, lines 1-8 for the extension being reversibly deformable.

Response to Arguments

8. Applicant's arguments with respect to claims 102-107, 109-133, 137-139, 141, 142, 145-149, 151-175 and 179-181 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

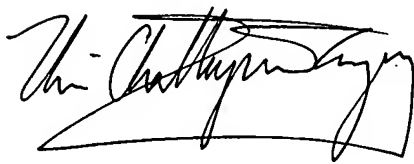
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached Monday through Thursday and every other Friday from 9:00am to 6:30pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmi Chattopadhyay

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David J. Isabella
Primary Examiner